Invitation to a meeting to discuss long acting Buprenorphine preparation, Buvidal

Dr Roya Vaziri, Humankind Medical Director

A long acting Buprenorphine preparation is now licenced by the European Medicines Agency. It has a tradename of Buvidal [1] and contains buprenorphine which is delivered by a FluidCrystal® technology as a subcutaneous injection ie under the skin.

The injections can be given weekly or monthly with different doses available.

Invitation to a meeting to discuss Buvidal

Humankind would like to invite commissioners, partners and other stakeholders to a meeting to discuss Buvidal. This is to be held on February, 2019, sponsored by Camurus.

The meeting will be in three parts covering research updates, cost benefit analysis, and logistics of delivery.

If you would like to be part of this meeting please contact Emma Haigh (ehaigh@nhs.net) by the 31st of January, who can also manage requests from those who wish to have further discussions with Dr Vaziri, as Humankind Medical Director.

About Buvidal

For those that are already receiving buprenorphine by mouth there is a conversion table to support transfer to the injectable formulation. The product licence states that individuals not already receiving buprenorphine, can only start the first weekly injection after a trial of an observed oral Buprenorphine dose.

There is an expectation that additional injection doses are needed in the first week. After a minimum of four weeks receiving weekly injections a conversion to monthly injections can take place.

There is no current published data around detoxification or withdrawal.

This injectable preparation is reported as showing efficacy when compared with buprenorphine/naloxone combination by mouth.

Buvidal trial assessment

Humankind Medical Director Roya Vaziri has reviewed the trial that took place at multiple sites across the USA, published in JAMA [2] .The trial had strong design

elements including it being randomised, double blind, double dummy, active controlled, flexible dose.

In summary, out of 600 assessed for eligibility, 428 subjects were chosen and randomly divided into two groups.

One group which received the buprenorphine injections (with placebo tablets) and the other group received placebo injections with an oral combination tablet of buprenorphine and naloxone.

The trial length was 24 weeks divided into a first phase lasting 12 weeks, when injections were given weekly and followed by a further 12 weeks in the second phase when injections were given monthly.

A higher percentage of urine samples were negative for illicit opioids in the group receiving the injection versus oral buprenorphine/naloxone. The interpretation of the data and outcomes is helped by understanding many design factors including: the definition of responder (based on self-report of no illicit drug use together with a urine test, at predefined times within the trial) and that the oral buprenorphine/naloxone was not supervised, but given either as weekly (in phase 1) or monthly (in phase 2) supply.

Dr Roya Vaziri said: “I am committed to evaluating this new long acting Buprenorphine preparation. Creating a space for the open and honest review of the benefits, risks and logistics will support us to move forward together and add to the clinical interventions that Humankind provides. This will be the first of many meetings to come to support collaborative working with the clinical department.”

1. https://www.ema.europa.eu/documents/product-information/buvidal-epar-product-information_en.pdf
2. Weekly and Monthly Subcutaneous Buprenorphine Depot Formulations vs Daily Sublingual Buprenorphine with Naloxone for Treatment of Opioid Use Disorder A Randomized Clinical Trial. JAMA Internal Medicine 178(6) · May 2018